II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Jason Skramsted
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Date Prepared: 20 January 2012

Trade Name: Reprocessed Femoral Compression Device

Classification Name: Clamp, Vascular, Reprocessed

Classification Number: Class II, 21 CFR 870.4450

Product Code: NMF

Predicate Devices:	The reprocessed femoral compression device is substantially equivalent to the SterilMed Femoral Compression Device (K012574) with secondary substantial equivalence to the St. Jude Medical FemoStop™ Gold Femoral Compression System(K080206).
Device Description:	The femoral compression device consists of an arch with a sterile pneumatic pressure dome and a connection tubing and belt. The device is applied on the patient with the dome over the femoral artery or vein and the belt around the patient. A sterile wound dressing is to be placed between the device and the patient making the device a "non-patient contacting device". The user controls the inflation of the dome by increasing or decreasing the pressure with a connected, manual pump (not provided). The dome applies a mechanical pressure over the spot where there is bleeding, while the arch and belt absorb and evenly distribute the opposite force from the dome. Only the femoral compression device is the subject of this submission; the integrated pump with a manometer is not included in the scope of this submission.
Intended Use:	The Reprocessed Femoral Compression Device is intended for use in the compression of the femoral artery or vein after catheterization.
Functional and Safety Testing:	Representative samples of reprocessed femoral compression devices were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F1929, ASTM F2096), and shelf life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, fatigue testing, and function testing. Performance testing shows the reprocessed femoral compression device to perform as intended.
Conclusion:	The reprocessed femoral compression device is substantially equivalent to SterilMed's Femoral Compression Device with secondary substantial equivalence to the St. Jude Medical's FemoStop™ Gold Femoral Compression System. This conclusion is based upon the devices' similarities in functional design (principles of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 3 2012

SterilMed, Inc.
c/o Mr. Jason Skramsted
Regulatory Affairs Specialist
11400 73rd Avenue North
Maple Grove, MN 55369

Re: K120204
Trade/Device Name: Reprocessed Femoral Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Clamp, Vascular, Reprocessed
Regulatory Class: Class II
Product Code: NMF, DXC
Dated: January 20, 2012
Received: January 23, 2012

Dear Mr. Skramsted:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120204

Device Name: Reprocessed Femoral Compression Device

Indications for Use:

The Reprocessed Femoral Compression Device is intended for use in the compression of the femoral artery or vein after catheterization.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120204